Attorney Docket No.: B0410/7280D1 U.S. App. No. 10/768,770

Filed: January 29, 2004 Amendment and Reply Inventors: Richard A. Gambale et al.

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The following <u>Listing of the Claims</u> will replace all prior versions and all prior listings of the claims in the present application:

Listing of The Claims:

1. (Presently amended) A method for stimulating angiogenesis within a muscle, comprising:

employing a delivery system for accessing the muscle, penetrating the muscle, and

operating the delivery system for enclosing within the muscle at least one body formed of a biocompatible material and dimensionally adapted for being enclosed within the muscle, wherein said body defines a lumen that is adapted to maintain an open cavity in the tissue sufficient to permit blood pooling in the lumen and the body comprises external projections configured to create cavities between the tissue and the body sufficient to permit blood pooling in the cavities, to thereby stimulate angiogenesis.

- 2. (Original) A method according to claim 1, wherein employing a delivery system includes employing a catheter delivery system.
- 3. (Original) A method according to claim 1, wherein employing a delivery system for accessing the muscle includes guiding a catheter delivery system through a patient's vascular system.
- 4. (Original) A method according to claim 1, wherein penetrating the muscle includes penetrating a muscle comprising the myocardial wall of a heart.
- 5. (Original) A method according to claim 1, wherein penetrating the muscle includes driving a distal portion of the delivery system into the muscle.
- 6. (Original) A method according to claim 1, wherein penetrating the muscle includes driving the at least one body into the muscle.

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muscle.

7. (Original) A method according to claim 1, wherein operating the delivery system includes operating a delivery system that substantially seals the at least one body within the

- 8. (Original) A method according to claim 1, wherein operating the delivery system for enclosing at least one body within the muscle includes implanting a plurality of bodies within the muscle.
- 9. (Original) A method according to claim 1, wherein operating the delivery system for disposing at least one body within the muscle includes implanting at least one body adapted for promoting blood pooling within the muscle.
- 10. (Original) A method according to claim 1, wherein operating the delivery system includes operating the delivery system for delivering into the muscle an agent for promoting angiogenesis.
- 11. (Presently amended) A method for stimulating angiogenesis within the tissue of a muscle, comprising:

accessing the muscle with a delivery system, penetrating the muscle, and

releasing within the muscle at least one body formed of a biocompatible material and dimensionally adapted for being enclosed within the muscle, wherein said body defines a lumen that is adapted to maintain an open cavity in the tissue sufficient to permit blood pooling in the lumen and the body comprises external projections configured to create cavities between the tissue and the body sufficient to permit blood pooling in the cavities, to thereby stimulate angiogenesis, said biocompatible material being capable of inciting an inflammatory reaction with the tissue of the muscle.

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12. (Original) A method for promoting angiogenesis within the tissue of a muscle, comprising:

accessing the muscle with a delivery system, penetrating the muscle,

releasing within the muscle at least one flexible body dimensionally adapted for implantation within the muscle, said body having been subjected to deforming stress prior to its release within the muscle and said body dynamically approximating the recovery of its native configuration after its implantation, and

withdrawing the delivery system from its proximity to the muscle.

13. (Original) A method for promoting angiogenesis within the tissue of a muscle, comprising:

accessing the muscle with a delivery system, penetrating the muscle,

releasing within the muscle a body formed of a heat responsive material, said body undergoing dimensional change upon exposure to intramuscular heat, and withdrawing the delivery system from its proximity to the muscle.

14-32. (Cancelled)

- 33. (New) A method according to claim 1 further comprising at least one opening in the body open to the lumen.
- 34. (New) A method according to claim 1 further comprising a drug releasing compound retained by a surface of the body.
- 35. (New) A method according to claim 34 wherein the drug releasing compound is contained within a lumen of the body.

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36. (New) A method according to claim 34 wherein the drug releasing compound is applied to a surface of the body by a coating.

- 37. (New) A method according to claim 34 wherein at least a portion of the body is formed from a drug releasing compound.
- 38. (New) A method according to claim 1 further comprising a radiation source carried by the body.
- 39. (New) A method according to claim 1, where the body is flexible and comprises a bellows for expanding and contracting responsive to muscle relaxation and contraction and wherein the external projections are defined by annular ripples.
- 40. (New) A method according to claim 1, where the body is flexible and comprises a plurality of tighter pitch spring sections connected by two open pitch spring elements, where the external projections are defined by the tighter pitch spring sections.
- 41. (New) A method according to claim 1, where the body is cone-shaped with a distal tip, and the external projections are a series of barbs on the external surface.
- 42. (New) A method according to claim 39, where the body further comprises at least one opening in the body open to the lumen and a drug releasing compound contained within the lumen of the body, where during contraction of the bellows the compound diffuses through the opening in the body.